REMARKS

Claims 1 and 2 have been amended to delete reference to hydrates, solvates and crystal forms and to change "diastereomers" to "stereoisomers". "Optionally substituted" has been deleted from the definition of the 3-8 membered ring contained in the definitions of R^2-R^4 and A. Claim 1 has also been amended to delete CF_3 from the definition of R^{10}, and to conform to the priority documents.

The alternative definition of R^2-R^4 regarding a ring system has been amended to limit it to the first ring system listed. Support for this embodiment is found on page 60 of the specification, third compound from the bottom. The definition of Q and W has been clarified and H has been eliminated from the definition of W.

For clarity and consistency with claim 2, the substituent Y in claim 1 has been renamed "Z". Z is now defined simply as H or C_{1-4} alkyl. R^{12} has been changed to R^{22} to avoid an inconsistency with claim 2. In addition, the definition of prodrugs from page 12 of the specification has been inserted.

In addition, in claim 2, the substituents defining R^1 have been renumbered to correspond to the analogous definition in claim 1. As A, W and prodrugs are not changed in definition from claim 1, the claim wording has been simplified to reflect this. The numbering of the R groups in the substituents describing R^2 has been amended to conform to the numbering in claim 1 as well.

For the most part, these changes are editorial and no new matter has been added. Entry of the amendment is therefore respectfully requested.

Priority

The Office asserts that the disclosures of the applications from which priority is claimed, AU2002/953255 filed 11 December 2002 and US 60/483,399 filed 26 June 2003 do not support the present claims as these documents are asserted not to disclose prodrugs and the definition for R^{10} does not conform to that of the present claims.

Applicants believe the Office is in possession of copies of both documents.

With respect to prodrugs, applicants respectfully point out that page 8 of the Australian application, and page 7 of the U.S. provisional, the second full paragraph of each, states that the invention encompasses pharmaceutical compositions containing prodrugs of the compounds of formula 1. Further, the definition of prodrugs, similar to that on page 12 of the present application is provided in these paragraphs. Therefore, priority is supported with respect to prodrugs.

With respect to R^{10}, R^{10} appears in claim 1 in the context of the formula $NR^{10}CONR^8R^9$ in the definition of R^2-R^4 and in claim 2 in the same context defining R^2. In order to conform to the priority document, the claims have been amended to make it clear that the definition of R^{10} corresponds to that in the priority documents as set forth on page 5 of the Australian application and page 4 of the U.S. provisional. As to claim 2. the superscripts in the definition of R^2 have been modified to correspond to those in claim 1 and the definition of R^{10} is similarly supported on pages 5 and 4 of the respective priority documents.

Accordingly, priority is properly accorded to the date of filing of the Australian application — 11 December 2002, and the application has been effectively filed in the U.S. as of 26 June 2003.

Restriction/Election of Species

Applicants confirm their previous elections of the invention and the species. Non-elected claims have not been canceled in view of the possibility of their rejoinder should the claims to the composition in the present case be allowed. Applicants understand that claims 11-13 and 15-17 are withdrawn from consideration.

Specification Objection

It is believed that the arrangement of the specification substantially conforms to that laid out by the Examiner on page 4 of the Office action. The Preliminary Amendment provides the cross-reference to related applications heading and paragraph so (a) and (b) are present; (c), (d) and (e) are not relevant to the present case. (f) Is present as the Field the Invention and Background on page 1; (g) the Brief Summary of the Invention appears on page 4. There are no drawings so (h) is not relevant. The Detailed Description of the Invention appears on page 6; Claims and Abstract are both present. No sequence listing is involved. Therefore, the specification conforms substantially to the suggested guidelines.

Claim Objections

These have been addressed by amendment; "diastereomers" has been replaced by "stereoisomers"; "R12" is no longer present in claim 2.

The Rejection under 35 U.S.C. § 112, Paragraph 1

The Office states that the specification is enabling for instances of formula I where Y in former claim 1 is H or C_{1-4} alkyl and where no two of R^2, R^3 and R^4 are joined to form a ring

system. Applicants note the definition of Y in formula II is not objected to. The amendments to the claims address this rejection directly. The definition of Y (now Z) in formula I is now limited to the acknowledged enabled H or C_{1-4} alkyl. The only ring system claimed is that supported on page 60 as described above. Accordingly, the rejection based on the definition of Y (now Z) in formula I and R^2-R^4 may be withdrawn.

Additionally, the Office asserts that hydrates, solvates and crystal forms are not supported by the specification.

These specific embodiments have been deleted from both claims 1 and 2. Applicants understand that such forms are generically covered, however the specific embodiments of these particular species are no longer articulated in the claims. Accordingly, this basis for the rejection under the first paragraph of § 112 is obviated.

The Rejections under 35 U.S.C. § 112, Paragraph 2

The first aspect of this rejection concerns the phrase "optionally substituted". This phrase has been deleted in each instance where it occurs, with one exception. The only instance in which "optionally substituted" has not been removed is in the definition of A where the substituents are spelled out.

The second basis for this rejection is the asserted unclarity of the limitation in claim 1 where Q is a bond and therefore W contains an incomplete valence. This has been clarified as noted. Either Q and W are both absent so that N and A are directly joined or W is present when Q is present as C_{1-4} alkyl. "Alkyl" has been changed to "alkylene" as it must be at least divalent — *i.e.*, bound both to N and A.

The obvious lack of clarity resulting from designating both the substituent on the pyrazine ring Y and the substituent on the phenyl group as $(CH_2)_nY$ has been remedied by substituting "Z" for "Y" as the designation for the pyrazine ring substituent.

Claim 3 was rejected as indefinite because of the phrase "at least a portion." Claim 3 has been reworded now simply to require that the compound is a mixture of both chiralities at the relevant carbon. Claims 4-8 have been amended to read on a compound wherein the mixture comprises at least 90% of the compound with *S* chirality at the relevant carbon. It is believed that this obviates the rejection.

Claim 9 is rejected as indefinite as one of the compounds contains a phosphate moiety. It is respectfully noted that this compound fits the definition of prodrugs as now set forth in claim 1 and as elucidated on page 12 of the specification. Phosphate derived esters are specifically mentioned on page 12 at line 19 thereof. Thus, this compound is properly included in claim 9.

The Rejections under 35 U.S.C. § 102

Claims 1 and 2 were rejected as assertedly anticipated by Ding, *et al., JACS* (2002) 124:1594-1596. It is noted that this document references similar compounds to those claimed wherein Q is CH and W is H. This embodiment has been deleted from the claims, thus obviating this basis for rejection.

Claims 1, 3-8 and 10 were rejected as anticipated by Burns, *et al.,* WO 02/060492.

Respectfully, as priority has been properly established as to filing in the U.S. as of 26 June 2003 in the present case and as WO 02/060492 has a publication date of 8 August 2002, *i.e.*, within one year of the date of the filing of 60/483,399, this document would be citable only

under 35 U.S.C. § 102(a). It is clear that WO 02/060492 is the work of the same inventors as those herein as the inventive entities are identical. Accordingly, this document may be removed as a reference. No *Katz* declaration should be needed in view of the identity of the "authorship" on the cited document and the inventive entity herein. Accordingly, this basis for rejection may also be withdrawn.

Double-Patenting

Claims 1-10 were provisionally rejected as double-patenting over US 10/581,534. A terminal disclaimer with respect to this application is submitted herewith.

Claims 1-3 and 10 were rejected as assertedly obviousness-type double-patenting over U.S. application 11/367,248. This application has been abandoned.

Claims 1-10 were rejected as double-patenting over the claims of U.S. 7,122,550. A terminal disclaimer with respect to this patent is also submitted herewith.

Conclusion

The claims have been amended for clarification. Entitlement to priority has been demonstrated. In addition, amendments have been made to overcome the formal rejections of the claims.

The rejection over the art has been obviated by amendment, and by demonstration of entitlement of priority. Double-patenting rejections are obviated by terminal disclaimers or abandonment of the referent applications.

Accordingly, applicants believe that claims 1-10 are in a position for allowance. Rejoinder of claims 11-13 and 15-17 and allowance of all pending claims is respectfully requested.

Should some outstanding issues remain that could be resolved over the phone, a telephone call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 415852000800.

Respectfully submitted,

Dated: December 29, 2009 By: / Kate H. Murashige /

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